



**The Freeze Drying of
Pharmaceuticals and Biologicals
Conference**
August 6 – 9, 2008
Great Divide Lodge
Breckenridge, Colorado



Final Conference Schedule

Wednesday, August 6

- 8:30 am.– 5:00 pm **Fundamentals of pharmaceutical freeze-drying**
A short course in the basics taught by Michael Pikal and Steve Nail for those new to the subject.
- 6:30 – 8:30 pm **Opening reception**
Sponsored by SP Industries

Thursday, August 7

- 7:30 – 8:15 am **Continental breakfast**
- 8:15 – 8:30 am **Introduction and overview of meeting**
Steve Nail, Ph.D.
Baxter Biopharma Solutions
- 8:30 – 9:00 am **Keynote Address**
Freeze Drying over the past decade: Yes, we have made progress!
Michael Pikal, Ph.D., Pfizer Distinguished Chair in Pharmaceutical Technology, University of Connecticut

Materials Characterization in Freeze-Drying, E. Trappler, Moderator

- 9:00 – 9:30 am **H-Bond network lifetimes as a diagnostic tool for freeze-dried formulations**
Marc Cicerone, Ph.D., NIST
- 9:30 – 10:00 am **Potential application of pairwise distribution function analysis to measurement of phase separation in freeze-dried solids**
David Engers, Ph.D., Aptuit, Inc.
- 10:00 – 10:30 am **Break**
- 10:30 – 11:00 am **Exploration of molecular motions most relevant to stability of freeze dried formulations**
Sumi Yoshioka, Ph.D., University of Connecticut
- 11:00 – 11:30 am **Thermal analysis of frozen solutions: Multiple glass transitions in amorphous systems**
Greg Sacha, Ph.D., Baxter Biopharma Solutions
- 11:30 am – noon **Panel Discussion** with audience participation (3 slide, 3 minute limit each)
Moderator: Alan MacKenzie, Ph.D.
- Noon – 1:30 pm **Lunch, Poster presenters will post presentations.**

Formulation Science, W. Friess, Moderator

- 1:30 – 2:00 pm **Stabilization of a lyophilized protein to gamma-irradiation: Implications for terminal sterilization of freeze-dried biopharmaceutical products**
Mark Manning, Ph.D., Legacy Biodesign, LLC
- 2:00 – 2:30 pm **H-D exchange for protein conformational analysis in the solid state**
Elizabeth Topp, Ph.D., University of Kansas
- 2:30 – 3:00 pm **Freeze-drying of vaccines containing colloidal aluminum adjuvants**
Ted Randolph, Ph.D., University of Colorado
- 3:00 – 3:30 pm **Break**

3:30 – 4:00	Interrelation of formulation and process development in freeze drying: A case study Feroz Jameel, Ph.D. Amgen
4:00 – 4:30 pm	Panel Discussion with audience participation Moderator: Alan MacKenzie, Ph.D.
4:30 – 7:00 pm	Wine and cheese reception ~ Cosponsored by Baxter Biopharma Solutions and Lyophilization Technology
4:30 – 6:00	Vendor Technical Briefs
4:30 – 7:00	Poster Presentations

Friday, August 8

7:30 – 8:30 am **Continental Breakfast**

Formulation Science, continued

8:30-9:00 am **Lyo cake stability prediction: General considerations and a case study**
Dirk Teagarden, Pfizer, St. Louis

Freeze Dry Process Design and Scale-Up, D.Q. Wang, Moderator

9:00 – 9:30 am **Freeze dry process optimization from a statistical analysis of the impact of variation in critical drying parameters**
Robin Bogner, Ph.D., University of Connecticut

9:30 – 10:00 am **User-friendly modeling of the freeze-drying process**
Stephanie Passot, Ph.D., AgroParisTech, INRA

10:00 - 10:30 am **Lyo cycle scale up: freeze-dryer characterization and mapping, heat transfer coefficients, and freeze-drying heat/mass transfer models**
Sumit Luthra, Ph.D., and Larry Gatlin, Ph.D., Pfizer

10:30 – 11:00 am **Break**

11:00 – 11:30 am **Freeze-drying cycle optimization facilitated by mathematical modeling and tunable diode laser absorption spectroscopy (TDLAS)**
Wei Kuu, Ph.D., Baxter Biopharma Solutions

11:30-12:00 am **Modeling of vapor flow in a freeze dryer**
Alina Alexeenko, Ph.D., Purdue University

12:00-12:30 am **Panel Discussion** with audience participation
Moderator: Alan MacKenzie, Ph.D.

Friday Afternoon:

Box Lunch and Open Time



Saturday, August 9

7:30 – 8:30 am **Continental Breakfast**

Freeze Dry Process Design and Scale-Up, continued

8:30 – 9:00 am **Choked flow and importance of mach I in freeze-drying process design**
Sajal Patel, University of Connecticut

9:00 – 9:30 am **A new freeze-drying facility: Description and lessons learned**
Ernesto Renzi, IMA Edwards

9:30 - 10:00 am **Monitoring and control of freeze drying using innovative software devices**
Antonello Barresi, Ph.D., Politecnico di Torino

10:00 - 10:30 am **Break**

Regulatory Considerations, Process Control and PAT, G. Winter, Moderator

10:30 – 11:00 am **Quality by design and its application to freeze dried product and process development**
Mansoor Khan, Ph.D., FDA

11:00 - 11:30 am **Measurement of end point of primary drying at production scale**
Alexander Schaepman, IMA Edwards

11:30 - noon	Mass flux by tunable diode laser absorption spectroscopy: Critical analysis issues and applications to product temperature measurement. Bill Kessler, Physical Sciences
Noon - 1:00pm	Lunch
1:00 – 1:30 pm	Process analytical technology in freeze drying: the “desired” state vs. reality Henning Gieseler, Ph.D., University of Erlangen
1:30 – 2:00 pm	Evaluation of advanced approaches to monitor product temperature during lyophilization Michael Wiggenghorn, LMU, University of Munich
2:00 - 2:30 pm	Panel Discussion with audience participation Moderator: Alan MacKenzie, Ph.D.
2:30 - 2:45 pm	Conference Wrap-up Gerhard Winter, Ph.D., University of Munich